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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/092,955 | 03/06/2002 | William L. Rohr | 022719-0022 | 7356 |

21125 7590 02/07/2006

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| EXAMINER |
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KENNEDY, SHARON E

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| ART UNIT | PAPER NUMBER |
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3767

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/092,955 | Applicant(s) ROHR ET AL. | |
| | Examiner Sharon Kennedy | Art Unit 3767 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7,8,12,14,15,17 and 20 is/are rejected.
- 7) ☐ Claim(s) 2, 6, 9-11, 13, 18 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>07/23/2002, pg 1 only</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action or the MPEP.

Information Disclosure Statement

Page 1 of the IDS submitted July 23, 2002 is submitted herewith, which has the initialed EP reference.

Claim Rejections - 35 USC § 102

Claims 1, 3, 5, 7, 8, 12, 14, 15, 17, 20 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Steil et al., US 6,558,351. Note is made of the Affidavit under Rule 131 submitted on May 24, 2004. The Steil's patent has a filing date of June 1, 2002. Steil's discloses a closed loop system for controlling insulin infusion. Note that signals from the sensor are stored. Note also Figure 37, which shows the continuous adjustment of insulin delivery based on the sensor readings. Regarding claim 3, note that the Steil sensor operates via electrodes placed into interstitial fluid, which anticipates the claims electrochemical sensor. Regarding claim 7, note figure 2, sensor apparatus 28 on the right side, and infusion apparatus 34 on the left side.

Claim Rejections - 35 USC § 103

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Steil '351. It would be obvious to one of ordinary skill in the art to input any type of drug with the Steil device dependent upon patient need.

Allowable Subject Matter


Claims 2, 6, 9-11, 13, 18 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. These claims point out that the invention has nothing to do with an insulin delivery device.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmens can be reached on 571/272-4965.

Information regarding the status of an application may be obtained by going to www.uspto.gov, clicking on "Status &IFW", entering the application number, and then clicking on one of the tabs to retrieve the appropriate information.


Sharon Kennedy
Primary Examiner
Art Unit 3762